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Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1997

DEBORAH EDDY AND THOMAS EDDY,

Petitioners,

v.

POLYMER TECHNOLOGY CORPORATION,
THRIFT DRUG, INC. AND
DR. JAMES H. LETHAM, O.D.,

Respondents.

On Petition For A Writ Of Certiorari To The Superior Court Of Pennsylvania

PETITIONERS' SUPPLEMENTAL BRIEF

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PETITIONERS' SUPPLEMENTAL BRIEF

Petitioners file this Supplemental Brief pursuant to Supreme Court Rule 15.8 to address the December 8, 1997 Brief for the United States as Amicus Curiae ("Amicus Brief") filed in *Smith Industries Medical Systems, Inc. v. Kernats*, No. 96-1405 (petition for cert. filed March 4, 1997),[1] and the proposed rule of the Food and Drug Administration ("FDA") appended thereto.[2]

Kernats presents the same issue as the present case – viz., whether the FDA's pre-market approval of a medical device results in pre-emption of state tort law with respect to the device. In its Amicus Brief (at 9, 18) the United States recognized that this is "an issue of substantial importance that has divided the lower courts," and that this division "would normally provide a strong justification for this Court to grant review and definitively resolve the conflict." However, the United States concluded that *certiorari* is inappropriate in *Kernats* because (1) the judgment in *Kernats* is not final; (2) the judgment in *Kernats*, denying preemption, is correct in the view of the United States; and (3) the FDA is proposing a rule that bears on the issue.

The present case differs from *Kernats* in that the court below reached the opposite result, holding all of Petitioners' claims preempted, and in so doing disregarded

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[1] The United States filed its Amicus Brief in *Kernats* in response to an order of this Court inviting the Solicitor General to file a brief expressing the views of the United States. *See Kernats*, 137 L. Ed. 2d 817 (May 12, 1997).

[2] The proposed rule has since been published at 62 Fed. Reg. 65384-65388 (Dec. 12, 1997).

the FDA's longstanding interpretive regulations. Petitioners submit that, in view of these differences, the United States's recommendation against *certiorari* in *Kernats* should not control this case. Alternatively, if the Court believes that the FDA's proposed rule is sufficiently important to warrant deferral of review, the Court should remand this case for reconsideration in light of that rule.

1. The judgment in the present case is final.

The United States points out that this Court may lack jurisdiction under 28 U.S.C. § 1257 to review the judgment in *Kernats* because that judgment is interlocutory rather than final. The petitioner in *Kernats* may yet prevail on state law defenses; and if it loses on the merits, it will again have an opportunity to seek discretionary review of its federal preemption claim in the Illinois Supreme Court.

In the present case, in contrast, the effect of the Pennsylvania Superior Court's judgment, coupled with the Pennsylvania Supreme Court's denial of review, is to put Petitioners out of court forever on all of their claims. No issues remain to be decided by the lower courts, and thus there will be no vehicle for a later appeal. The judgment upon which review is sought in this case is therefore a "final judgment" for purposes of 28 U.S.C. § 1257.

2. The judgment in the present case is incorrect.

The second ground cited by the United States for recommending against *certiorari* in *Kernats* is that, although the United States disagrees with the reasoning of the lower court in that case, in its view the judgment denying preemption is correct. This reason clearly does not apply to the present case. The court below reached the opposite result to that in *Kernats*, holding that all state law causes of action are pre-empted by virtue of the FDA's pre-market approval. This result is directly contrary to the position of the United States as set forth in its Amicus Brief at 14-18. To the extent that the correctness of the judgment in *Kernats* is a factor militating against *certiorari* in that case, the incorrectness of the judgment in the present case should militate in favor of a grant of *certiorari* herein.

3. The FDA's issuance of a proposed clarifying regulation should not forestall review.

Unlike the first two grounds, the third ground proffered by the United States in opposition to *certiorari* in *Kernats* the FDA's issuance of a new proposed rule does apply to the present case. However, the proposed rule is not sufficient to warrant putting off resolution of the important issue posed in this case, for three reasons.

First, the proposed rule does not represent a departure from the FDA's prior interpretation. Rather, it is merely a restatement of the agency's long-standing and oft-repeated position. As the FDA explains:

> This proposed rule would make no change in the agency's prior or current construction of

> section 521 of the act[, 28 U.S.C. § 360k]. Rather, the rule would simply clarify and codify the agency's longstanding interpretation of the scope of section 521 of the act as generally not preempting available legal remedies, including State common law tort claims.

Appendix to Amicus Brief at 15a.[3] Although it may sometimes be appropriate to defer review until the lower courts can react to a pathbreaking new administrative interpretation, this factor does not apply where, as here, the proposed regulation reflects the same interpretation that has been available to guide the courts for nearly 20 years.[4]

Second, waiting to see if an agency can diffuse a conflict among the courts by restating its own view will render the ultimate resolution of legal questions less efficient, by requiring a second round of intermediate appeals before an issue can reach this Court. Under the practice urged by the United States, when a conflict arises among the courts on an issue of statutory interpretation, the issue would first be referred to an agency to weigh in on one side or the other, and only after a new series of suits and appeals revealed a continuing conflict would

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[3] *See also, e.g., id.* at 12a (stating that the interpretation in the proposed rule is based "primarily on the language of section 521 of the act and *the agency's past regulatory interpretation*") (emphasis added).

[4] *Cf. id.* at 4a-5a (stating that 21 C.F.R. § 808.1(d), which embodies the FDA's restrictive interpretation of 21 U.S.C. § 360k, "has remained substantially unchanged for nearly 20 years").

the courts and the parties receive the benefit of this Court's guidance.

It is significant that the FDA's proposed rule has only very recently been proposed. It will take some time before it is promulgated as a final regulation, and considerable further time before new cases in which the regulation may be considered could work their way up through the lower courts and become ripe for review in this Court. In the meantime, if the suggestion to defer review were accepted, not only the decisions for which *certiorari* is sought based on the present split among the courts, but numerous other cases that may be controlled by those decisions, would fall by the wayside. The result would be that the lower courts continue to be burdened with uncertainty about the law and that a potentially large group of litigants (on the ultimately prevailing side of the issue) would see the issue resolved too late to afford them relief.

Third, as a practical matter it is hardly to be expected that the lower courts, having divided sharply in the face of the FDA's long-term adherence to the same position it now espouses, will suddenly achieve unanimity due to the FDA's formal reaffirmation of its position. A change in position is especially unlikely in the present case, as the Pennsylvania courts have already shown a disinclination to follow the FDA's guidance on the issue at hand.[5]

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[5] Although Petitioners emphasized the FDA's regulations in the courts below, the opinions herein make no mention of those regulations.

Petitioners believe that the foregoing considerations, coupled with the undoubted importance of the issue presented herein, justify a grant of *certiorari* in this case. In the alternative, if the Court believes that lower courts' consideration of the FDA's proposed rule might eliminate the conflict or focus the issues for review, Petitioners request that the Court remand this case to the Superior Court of Pennsylvania for reconsideration in light of the proposed rule.

Respectfully submitted,

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